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**VIA CM/ECF & HAND DELIVERY**

The Honorable Leonard P. Stark  
United States District Court  
For the District of Delaware  
844 North King Street  
Wilmington, DE 19801

REDACTED  
PUBLIC VERSION

**Re: Cosmo Technologies Limited, et al. v. Actavis Laboratories FL, Inc.  
C.A. No. 15-164 (LPS)**

Dear Chief Judge Stark:

Pursuant to the Court's August 4, 2016 Order (D.I. 170), defendant Actavis Laboratories FL, Inc. ("Actavis") writes in response to Plaintiffs' discovery dispute letter dated August 24, 2016 (D.I. 173).

Plaintiffs' letter does not identify a single issue where a physical or chemical test of Actavis's excipients would be probative. Instead, Plaintiffs rely on the notion that the excipients are "potentially relevant," far short of the Fed. R. Civ. P. 26(b)(1) requirement that discovery be limited to matters that are proportional to the needs of the case.

Excipients are not automatically relevant to a pharmaceutical patent. *See Orexo AB v. Actavis Elizabeth LLC*, No. 14-829-SLR, D.I. 148 at 2-3 (D. Del. Nov. 20, 2015) (Ex. 1) (affirming denial of request for raw ingredients and noting the absence of case law obligating a defendant "to provide samples of raw materials in addition to samples of the finished ANDA product"); *Shire Pharm. Dev. Inc. v. Amneal Pharms. LLC*, No. 15-cv-2865, D.I. 75 at 1 (D.N.J. Mar. 9, 2016) (Ex. 2) (denying request for excipient and ingredient samples). Even the transcript cited by Plaintiffs notes that the requested excipients were relevant to only two of the six patents-in-suit in that case, making them irrelevant to the remaining four. D.I. 173 at Ex. 3, *Supernus Pharms. Inc. v. Actavis, Inc.*, No. 14-cv-06102, D.I. 133 at 5 (D.N.J. Mar. 3, 2016). Without some indication that these materials are actually relevant or useful to this case, Plaintiffs are not entitled to request several pounds of pharmaceutical excipients on a fishing expedition.

In this case, the disputes concerning the unproduced samples relate only to their behavior and character within Actavis's ANDA product, not their chemical characteristics in isolation. [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] Although Actavis does not object to producing samples of individual excipients where analysis of those excipients is relevant to the case, requiring Actavis personnel to locate, measure, package and ship samples of sixteen irrelevant ingredients is unduly burdensome.

Actavis recognizes that excipients may sometimes be relevant and proportional to the needs of a case. [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] See Ex. 3 at 3. [REDACTED]  
[REDACTED]  
[REDACTED], Actavis understands that any dispute concerning this excipient is resolved. *See generally* Ex. 3.

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] It defies explanation how physical or chemical testing of these excipients would be relevant to any dispute or why production of these excipients is necessary.

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] Actavis repeatedly invited Plaintiffs to explain how physical or chemical testing of excipients might be probative to any of these disputes, and Plaintiffs repeatedly declined to do so. *See* Ex. 5 at 3, Email from S. Sherry, Apr. 15, 2016 (requesting explanation); *id.* at 1, Email from S. Sherry, May 20, 2016 (requesting explanation); Ex. 3 at 2-3, Email from S. Sherry, June 22, 2016 (noting lack of explanation); *id.* at 1, Email from S. Sherry, June 29, 2016 (noting lack of explanation); *see also id.* at 1-2, Email from D. Conca, June 23, 2016 (offering purported explanation that “the excipients are relevant because the patents claim, among other things, pharmaceutical

formulations made up of various components” and “Actavis's excipients make up its pharmaceutical formulations”).

Actavis has always been willing to produce samples of excipients for which physical testing is reasonably relevant and proportional to the needs of the case [REDACTED] [REDACTED] See Ex. 3; Ex. 5. However, for samples of the remaining excipients in the ANDA product, there is no apparent relevance or proportionality, and Plaintiffs have refused to explain any non-apparent utility to their production.

For at least the foregoing reasons, Actavis respectfully requests that the Court deny Plaintiffs' request for an order requiring production of the excipient samples.

Respectfully,

*/s/ David A. Bilson*

David A. Bilson (#4986)

cc: All counsel of record